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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

TRAN, MY CHAU T

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/674,819

Applicant(s)

AOMATSU, AKIRA

Examiner

MY-CHAU T. TRAN

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28,35-37,40 and 41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28,35-37,40 and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/02/2005 has been entered.

Application and Claims Status

2. Applicant's amendment and response filed 11/07/2005 is acknowledged and entered. Claims 29-34, 38-39, and 42 have been cancelled. Claims 28 and 41 have been amended.
3. The amendment filed on 02/21/2004: cancelled claims 1-27; and added claims 28-42.
4. The amendment filed on 04/20/2003: added claims 22-27.
5. Claims 28, 35-37, 40, and 41 are pending.

Election/Restrictions

6. The instant species election requirement is still in effect as there is no allowable generic or linking claim. Applicant has elected the following species for the elected invention (Claims 28, 35-37, 40, and 41) in the reply filed on 03/08/2005:

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- a. A *single specific* species of humectant. Applicant has elected propylene glycol.
 - b. A *single specific* species of auxiliary agent. Applicant has elected hydroxypropylcellulose.
 - c. A *single specific* species of neutral amino acid. Applicant has elected glycine.
7. Claims 29, and 31-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to *nonelected species*, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 03/08/2005. *However*, applicant has cancelled claims 29, and 31-34 in the amendment filed 11/07/2005.
8. Claims 28, 35-37, 40, and 41 are under consideration in this Office Action.

Priority

9. This instant application is a 371 of PCT/US99/10,186 filed 05/10/1999, which claims benefit to a foreign application, which is JAPAN 133112/98 filed 05/15/1998 under 35 U.S.C 119(a)-(d). Thus, the instant application is granted the benefit of priority for PCT/US99/10,186 filed 05/10/1999, and foreign priority to JAPAN 133112/98 filed 05/15/1998.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 28, 35-37, 40, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jao et al. (US Patent 5,660,861) and Giacini et al. (US Patent 5,302,373).

Jao et al. disclose a dosage form for delivering an antiepileptic drug and the method of making the dosage form (see e.g. Abstract; col. 1, lines 9-17; col. 3, line 66 thru col. 4, line 5; col. 10, line 65 thru col. 13, line 44). The dosage form comprises the form of a tablet or capsule (see e.g. col. 5, lines 14-26; col. 15, lines 34-53; fig. 1). The dosage form comprises an antiepileptic drug such as gabapentin (refers to the instant claimed 4-amino-3-substituted butanoic acid derivative, i.e. gabapentin) (see e.g. col. 6, lines 52-67; col. 17, line 23 thru col. 18, line 27), osmagent such as sorbitol (see e.g. col. 7, lines 42-52), and exterior coating such as hydroxypropylcellulose (refers to instant claimed auxiliary agent, and the elected species of hydroxypropylcellulose) (see e.g. col. 9, lines 8-25; col. 17, lines 23-52). The method comprises mixing the drug with the composition forming ingredients (see e.g. col. 12, line 63 thru col. 13, line 24).

Additionally, The features of remaining dependent claims are either specifically described by the reference, or constitute obvious variations in parameters which are routinely modified in the art (e.g. the percentage of each compounds in the composition), and which have not been described as critical to the practice of the invention.

The composition of Jao et al. differs from the presently claimed invention by failing to include a type of humectant that is propylene glycol.

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Giacin et al. disclose a mouthwash composition (see e.g. Abstract; col. 1, line 60 thru col. 2, line 2). The composition comprises a humectant such as propylene glycol, and sorbitol (see e.g. col. 2, lines 29-33). The humectant adds body and a pleasant mouth feel (see e.g. col. 2, lines 29-33).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a type of humectant that is propylene glycol as taught by Giacin et al. in the composition of Jao et al. One of ordinary skill in the art would have been motivated to include a type of humectant that is propylene glycol in the composition of Jao et al. for the advantage of providing a humectant that adds body and a pleasant mouth feel (Giacin: col. 2, lines 29-33) since both Jao et al. and Giacin et al. disclose a pharmaceutical excipient such as sorbitol (Jao: col. 7, lines 42-52; Giacin: col. 2, lines 29-33). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the combination of Jao et al. and Giacin et al. because Giacin et al. disclose that sorbitol, propylene glycol, and glycerol are functionally equivalent humectant (Giacin: col. 2, lines 29-33).

Withdrawn Objection(s) and /or Rejection(s)

12. The rejection of claims 28, 36, 40, and 41 under 35 USC 102(b) as being anticipated by Jao et al. (US Patent 5,660,861) has been withdrawn in light of applicant's amendments of claims 28 and 41 wherein the humectant is propylene glycol.

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13. The rejection of claims 28, and 35-42 under 35 USC 103(a) as being obvious over Jao et al. (US Patent 5,660,861) and Robson et al. (US Patent 4,126,684) has been withdrawn in view of applicant's amendments of claims 28 and 41 wherein the humectant is propylene glycol.

Response to Arguments

14. Applicant's arguments directed to the rejection under 35 USC 103(a) as being unpatentable over Jao et al. (US Patent 5,660,861) and Giacini et al. (US Patent 5,302,373) for claims 28, 35-37, 40, and 41 were considered but they are not persuasive for the following reasons.

Applicant contends that the combine teachings of Jao et al. and Giacini et al. is not obvious over the presently claimed invention because is not obvious over the presently claimed method because 1) applicant argue unexpected result with regard to the combination of propylene glycol and gabapentin or pregabalin such that the '*humectants such as propylene glycol will stabilize formulations containing gabapentin or pregabalin*' and 2) '*the references list a few humectants among many excipients*'. Thus, the combine teachings of Jao et al. and Giacini et al. are not obvious over the presently claimed invention.

Applicant's arguments are not convincing since the combine teachings of Jao et al. and Giacini et al. do render the invention of the instant claims *prima facie* obvious.

First in response to applicant's arguments of unexpected result with regard to the combination of propylene glycol and gabapentin or pregabalin such that the '*humectants such as propylene glycol will stabilize formulations containing gabapentin or pregabalin*', the examiner recognizes that objective evidence, which must be factually supported by an appropriate affidavit

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or declaration to be of probative value, includes evidence of unexpected results... See, for example, *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984) ("It is well settled that unexpected results must be established by factual evidence"). Lastly, any differences between the claimed invention and the prior art may be expected to result in some differences in properties. The issue is whether the properties differ to such an extent that the difference is really unexpected. *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (In MPEP § 716.02).

Second in response to applicant's arguments that '*the references list a few humectants among many excipients*', the examiner recognized that a genus does not always anticipate a claim to a species within the genus. However, when the species is clearly named, the species claim is anticipated no matter how many other species are additionally named. See MPEP § 2131.02, *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990), and *In re Sivaramakrishnan*, 673 F.2d 1383, 213 USPQ 441 (CCPA 1982). In this case Giacini et al. clearly cited the species of propylene glycol.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
January 20, 2006

Red
FACULTY MEMBER
FACULTY EXAMINER